REMARKS & ARGUMENTS

After entry of this paper claims 1-3, 5-14 and 46-57 are pending.

35 U.S.C. § 112, first paragraph

The Office rejected claims 1-14 and 46-51 as allegedly not enabled because it would require undue experimentation to practice the claimed invention.

To establish and maintain a rejection under 35 U.S.C. §112, first paragraph, the Office must provide logical reasoning to support its position. The Office must "explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi and Horton*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971). The Office must advance "substantive reasons why the instant specification is non-enabling." "Mere broad generalizations and allegations are insufficient for holding of non-enablement." *Ex parte Goeddel* 5 U.S.P.Q. 2d 1449 (B.P.A.I. 1987). The first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. *In Re Vaeck* 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991), *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.* 224 U.S.P.Q. 409 (Fed. Cir. 1984). It is irrelevant whether objective enablement is based on working examples or on broad terminology. *In Re Vaeck*, supra, *Atlas Powder Co.*, supra. To meet the requirement under the first paragraph of § 112, the specification, when filed, must enable one skilled in the particular art to use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988), *Ex parte Forman* 230 U.S.P.Q. 546 (B.P.A.I. 1986). In addition, even if some of the claimed embodiments were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude . . . possible inoperative substances . . . ." *Atlas Powder Co.*, supra, *In re Dinh-Nguyen*, 492 F.2d 856 (C.C.P.A. 1974).

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *In re Wands, supra*. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Ex parte Jackson, et al.*, 217 U.S.P.Q. 804 (B. P. A. I. 1982), *In re Ranier, et al.,* 146 U.S.P.Q. 218 (C.C.P.A. 1965).

Applicants have amended claim 1 to change the scope of compounds that the claims recite. The compounds recited in the amended claims contain an N-linked R^4 moiety such as $-NH_2$, $-NHR^{PR}$, a carbamate or an amide.

In addition, the Office's attention is directed to the declaration by Dr. Reading that accompanies this paper. The compound that claims 53 and 56 recite, 3β-hydroxy-17β-aminoandrost-5-ene, was used to treat blood cell deficiencies in rodents and primates. The blood cell deficiencies were induced by exposure to radiation or a myelosuppressive agent such as carboplatin. Administration of suitable amounts of 3β-hydroxy-17β-aminoandrost-5-ene and several compounds resulted in amelioration of deficiencies including neutropenia thrombocytopenia and anemia.

Applicants direct the Office's attention to the teaching in the application, including (1) example 38 beginning at paragraph 1270, which provides detailed protocols for modulating hematopoiesis, (2) examples 39 and 40 beginning at paragraphs 1283 and 1293, which provide detailed human clinical protocols for use of compounds within the scope of the claims, (3) the specification beginning at paragraph 602, which provides detailed discussion of methods to make, prepare and use formulations that contain the compounds, and (4) the specification beginning at paragraph 602, which provides detailed discussion of treatments for blood cell deficiencies. *Ex parte Jackson, et al.*, *In re Ranier, et al.,* cited above. Applicants respectfully request that the Office take into account the

detailed teaching the specification contains coupled with the evidence of efficacy described in Dr. Reading's declaration.

In view of the foregoing, Applicants respectfully submit that the presently claimed subject matter is enabled. Applicants request reconsideration and withdrawal of the rejection.

Double patenting

The Office provisionally rejected claims 1-14 and 46-57 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-37 of copending application No. 10/651,515 and claims 1-37 of copending application No. 10/728,400. Applicants respectfully traverse the rejection and note that this rejection is not procedurally ripe for consideration. Because of this, Applicants request the Office to hold this provisional rejection in abeyance until patentable subject matter is identified in any of these applications. Once patentable subject matter is identified, Applicant can properly address this issue, which will depend on the scope of allowable subject matter in one or more of these applications to guide the type of claim amendments that may be necessary.

Conclusion

Applicants' representative can be reached at the number given below if the Office has any questions or would like to address any other matters that may arise.

Respectfully submitted,

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